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DEUTSCHLAND

Vienna, 2 March 2016
Global/Glyphosat16 / u / 3A

- Reported parties:**
1. Responsible representative of
Monsanto Europe S.A.
Avenue de Tervuren 270-272
BEL-1150 Brussels
 2. Responsible representative of
Monsanto Agrar Deutschland GmbH
Vogelsanger Weg 91
D-40470 Düsseldorf
 3. Responsible representative of
Bundesinstitut für Risikobewertung (BfR)
Max-Dohrn-Str. 8-10
10589 Berlin
 4. Responsible representative of
European Food Safety Authority (EFSA)
Via Carlo Magno 1A
ITA-43126 Parma
 5. Unknown perpetrators, particularly in 1.-4.
- Reporting party:**
1. GLOBAL 2000
Neustiftgasse 36, 1070 Vienna
Austria
and
five others (see overleaf)
- Represented by:**
- Dr. Josef Unterweger
Buchfeldgasse 19a
1080 Vienna
Power of attorney granted
- Regarding:**
- Suspicion pursuant to section 263 Strafgesetzbuch (German Criminal Code) and sections 30 and 130 Ordnungswidrigkeitengesetz (German Administrative Offences Act)

Statement of facts

One copy

Two annexes (one copy each)

Reporting parties:

1. **GLOBAL 2000**
Neustiftgasse 36,
1070 Vienna
Austria
2. **Nature & Progrès Belgique,**
rue de Dave 520,
B-1500 Jambes,
Belgium
3. **Génération Futures**
179 rue Lafayette
75010 Paris
France
4. **Pesticide Action Network UK**
The Brighthelm Centre
North Road
Brighton
BN1 1YD
5. **Pesticide Action Network Europe**
Rue de la Pépinière 1
B-1000, Brussels
Belgium
6. **WeMove Europe SCE mbH**
Liegnitzer Str. 14
10999 Berlin
Germany

Represented by:

Dr. Josef Unterweger
Buchfeldgasse 19a
1080 Vienna
Power of attorney granted

The following

statement of facts

is submitted.

I. Statement of facts

1. GLOBAL 2000 is an Austrian environmental organisation which is recognised by the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management pursuant to recognition notice BMLFUW-UW.1.4.2/0035-V/1/2005 dated 17 May 2005. Its non-profit activities relate to protection of the environment, protection of health and the prevention of disasters.

Nature & Progrès Belgique, Générations Futures, Pesticide Action Network UK, Pesticide Action Network Europe und WeMove Europe SCE mbH are environmental organisations.

2. The reported parties

2.1. Monsanto

Monsanto Europe S.A. is the parent company of Monsanto Agrar Deutschland GmbH. Both companies are part of the Monsanto Group, one of the world's largest manufacturers of pharmaceuticals, chemicals, genetic modification technology and seeds. Monsanto produces the pesticide glyphosate, which accounts for around 40% of the company's income in Germany.

2.2. Bundesinstitut für Risikobewertung (BfR, Federal Institute for Risk Assessment)

The BfR is a German federal government authority with legal capacity. The Institute's activities include matters related to the approval of pesticides.

2.3. European Food Safety Authority (EFSA)

The EFSA's responsibilities include assessing the authorisation of pesticides and providing scientific opinions to the European Commission, European Parliament and the European Union's member states.

3. Facts of the case

3.1. Glyphosate is a weed killer which is produced and distributed by Monsanto among others. Glyphosate is used all over the world for weed control in agriculture, horticulture, industry and private households. Glyphosate is non-selective in terms of the plants it affects, but crop plants can be genetically engineered to make them glyphosate-resistant. In volume terms, glyphosate has been the most widely used ingredient in herbicides worldwide for years.

(Source: Wikipedia, accessed on 28 February 2016)

3.2. On 20 March 2015, the International Agency for Research on Cancer (IARC), part of the World Health Organisation (WHO), classified glyphosate as "probably carcinogenic to humans".

Under Regulation (EU) No 1107/2009 concerning the placement of plant protection products on the market (Pesticide Regulation), active substances that are carcinogenic may not be authorised in the EU. Existing authorisations may not be extended.

3.3. The authorisation for glyphosate in Europe expires in 2016. Monsanto is the leading producer and distributor of glyphosate. Under the leadership of Monsanto Europe S.A., producers and distributors came together in May 2012 to request an extension of the authorisation.

In the application for extension of the authorisation, Monsanto also declared that glyphosate had "no oncogenic potential". This claim was backed up using five carcinogenicity studies performed on laboratory mice.

The BfR accepted Monsanto's assessment, which stated that glyphosate was not carcinogenic.

On 20 March 2015, the WHO's International Agency for Research on Cancer classified glyphosate as "probably carcinogenic to humans".

Following the WHO's classification of glyphosate as a Group 2A carcinogen, the BfR reviewed the assessment of the cancer studies submitted by Monsanto for the first time.

During this review, it transpired that the request for an extension made under the leadership of Monsanto Europe S.A. was based on animal studies that had not been properly or professionally evaluated and interpreted.

In particular, five carcinogenicity studies on laboratory mice were assessed and interpreted using a less sensitive statistical evaluation procedure (comparisons of pairs) than the trend test recommended in the applicable OECD guidelines. This obscured the actual significant carcinogenic effects (present in all five industry studies submitted) in four out of five studies.

Pursuant to the Pesticide Regulation, active substances that show a significant carcinogenic effect in at least two independent animal tests may not be authorised in the EU. Existing authorisations may not be extended. When assessed in accordance with OECD standards, these studies, which were included in the application for extension, prove

that glyphosate caused cancer in mice in five carcinogenicity tests carried out independently of one another in terms of time and location.

If the request for extension prepared under the leadership of Monsanto Europe S.A. had not wrongly asserted that glyphosate had “no oncogenic potential”, the request for extension would have been rejected immediately.

The BfR was informed that the assessment of the animal studies in the extension application had not been carried out in compliance with OECD standards and that the estimation of cancer risk was incorrect.

The BfR did not revise its point of view, but continued to endorse Monsanto's opinion and then submitted an opinion to the European Food Safety Authority (EFSA) that ran counter to the facts. Besides contradicting itself, this opinion was based on incorrect data that was in violation of professional standards.

In spite of the available study results, the BfR continued to adhere to its original conclusion that classifying glyphosate as a carcinogenic would not be appropriate.

The EFSA accepted the BfR's erroneous assessment without question. Although 96 international researchers described the EFSA's conclusions as “scientifically unacceptable”, “fundamentally flawed” and “misleading” in an open letter to the European Commission, the Agency continued to stand by its conclusion that glyphosate should not be classified as a carcinogen – even though this ran counter to both the facts and the scientific evidence.

Proof:

- Regulation (EC) No 1107/2009 concerning the placement of plant protection products on the market and repealing the Council Directives 79/117/EEC and 91/414/EEC (Pesticide Regulation)

3.4. Criminal convictions for scientific fraud

"In two cases, the US Environmental Protection Agency (EPA) convicted laboratories which had been commissioned by Monsanto, among others, to conduct glyphosate studies for knowingly falsifying test results.

The Department of Justice closed Industrial Biotest Laboratories (IBT Labs) in 1978. In 1983, the management was found guilty of, among other things, falsifying statements and falsifying scientific data which were submitted to the government.

In 1991, the owners of Craven Laboratories, as well as several employees, were indicted and convicted of 20 similar serious criminal offences.

Monsanto declared that the studies concerned had been repeated, and that the EPA certification of Roundup was no longer based on studies conducted by Craven Labs."

(Source: Wikipedia, accessed on 29 February 2016)

Proof:

- Backgrounder: Testing Fraud: IBT and Craven Labs (PDF; 100 kB), Monsanto Imagine, June 2005

- Schneider, K. 1983. Faking it: The case against Industrial Bio-Test Laboratories. The Amicus Journal (Spring): 14-26. Available at PlanetWaves.net.

- US EPA: EPA FY 1994 Enforcement and Compliance Assurance Accomplishments Report (PDF; 1.3 MB). 1994.

3.5. Subjective components of the offence

Studies on glyphosate commissioned by Monsanto are notorious for flagrant scientific fraud and falsification.

Despite knowledge of this circumstance, the BfR accepted the statements made in the extension application submitted by Monsanto as true, without subjecting them to further examination.

Following indications that Monsanto had – once again – made incorrect statements that obscured statistically significant carcinogenic effects, the BfR not only failed to revise the obviously incorrect statements, but also submitted an opinion in support of the extension application that ran counter to the facts.

Despite indications of the shortcomings of the BfR's assessment, the EFSA accepted its arguments and conclusions, and announced, in contradiction of the available study results, that it did not consider the classification and labelling of glyphosate as a carcinogen to be appropriate.

All of the reported parties are guilty of acting intentionally.

4. Payment of fees

In 2011, Monsanto reported a net profit of USD 1.6 billion on revenues of USD 11.8 billion. Around 27% of its income comes from the production and sale of herbicides. The best known product is glyphosate, which is distributed under various brand names, in particular Roundup.

Glyphosate accounts for around 40% of Monsanto's revenue in Germany.

5. Section 263 German Criminal Code

The reported parties acted intentionally.

The actions constituting the offence were taken by the parties in order to enrich themselves or a third party, and in any case to enrich Monsanto Europe S.A. and Monsanto Agrar Deutschland GmbH.

The enrichment is illegal, because it violates legal prohibitions, namely sections 223 *et seq* and 263 German Criminal Code, as well as European Union law, namely the Pesticide Regulation and Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

Any party using false or falsified data, or other such proof, commits serious fraud in the meaning of section 263 German Criminal Code.

In particular, the five carcinogenicity studies conducted on laboratory mice, which were submitted by the applicants in May 2012 under the leadership of Monsanto, were not assessed and interpreted in compliance with the applicable OECD guidelines. In this way, under the leadership of Monsanto, an extension application was submitted which obscured the fact that significant carcinogenic effects were evident in all five mice studies and that glyphosate did not fulfil the prerequisites for authorisation pursuant to the Pesticide Regulation.

The damage significantly exceeds EUR 300,000 if a single person develops cancer due to the actions reported.

The reported parties committed the actions on a commercial basis, meaning that they were committed repeatedly with the intention of generating continuous income which is not inconsequential.

Monsanto commissioned glyphosate studies in at least two known cases connected to scientific fraud, in which the investigating laboratory was eventually convicted.

6. Competence

The actions constituting the offences occurred in Germany.

Glyphosate is probably carcinogenic to humans (WHO, 2015).

Glyphosate is applied in large quantities in Germany, both in agriculture and by amateur gardeners. Glyphosate residues have been found in the population. Placing carcinogenic products on the market is sufficient to cause cancer. This could be considered bodily injury, or even homicide.

Customers were deceived in the expectation that they were acquiring products which **"do not have any harmful effect on human or animal health or any unacceptable effects on the environment"**

(Regulation (EU) No 1107/2009 [Pesticide Regulation], recital 8, last sentence)

and are in no way **likely to have a carcinogenic effect** on humans.

The consequences of the actions of moral turpitude occurred in Germany. Therefore, the German courts are competent to adjudicate on this matter.

Proof:

- As above
- Submitted as one
- Analysis of the description and assessment of five cancer studies on mice within the scope of the reapproval proceedings for the active ingredient glyphosate, Dr. Peter Clausing, 29 February 2016
- Open letter dated 27 November 2015 from Professor Christopher J. Portier and 97 others to EU Commissioner Vytenis Andriukaitis (uncertified translation together with English language original)

II. Status of the reporting parties as parties to the proceedings

The reporting parties record that as environmental organisations, they also have access to the law in court proceedings concerning the environment, including the right to raise legal remedies that enable violations of the law by public authorities or private persons to be effectively reprimanded.

(Aarhus Convention Compliance Committee ACCC/C/2011/63, findings paragraph 66)

For all of these reasons, the reporting parties make the following

request

- to record the evidence offered
- to examine the statement of facts in terms of its relevance under criminal law
- to keep the reporting parties informed of the progress of the proceedings.

The reporting parties:

- **GLOBAL 2000 Environmental Protection Organisation**
- **Nature & Progrès Belgique**
- **Génération Futures**
- **Pesticide Action Network UK**
- **Pesticide Action Network Europe**
- **WeMove Europe SCE mbH**